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IN THE

Supreme Court of the United States

BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, MINNESOTA MINING AND MANUFACTURING COMPANY AND UNION CARBIDE CORPORATION,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*[1]

Advanced Medical Technology Association ("AdvaMed") is the largest medical technology association in the world, representing more than 1,200 medical device, diagnostic and

[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus* states that no counsel for a party has authored this brief in whole or in part, and that no person or entity, other than the *amicus*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

health information system manufacturers.[2] AdvaMed's members manufacture 90 percent of the $75 billion of health care technology purchased annually in the United States and more than 50 percent of the $175 billion purchased around the world annually.

AdvaMed's members are innovators of technologies that save lives and increase the quality of life for hundreds of thousands of patients every year. For example, technological breakthroughs such as coronary stents, implantable defibrillators and minimally invasive bypass surgery have helped reduce the death rate from heart disease by 40 percent since 1980.

In addition, medical technology reduces procedure times, hospital stays and patient recovery times and enables many treatments to be shifted to less costly sites of care. Coronary stenting, an effective alternative to open heart bypass surgery, for example, costs one-half as much, takes one-half the time to conduct and reduces the hospital stay from five or six days to one day.

AdvaMed's members spend an enormous amount of money—roughly $9 billion annually—on research and development of these innovations. On a percentage of sales basis, this investment constitutes more than four times the average spent on research and development by manufacturers in other industries.

Although they have a large positive impact on the health of patients, medical technology companies are by no means all large corporations. In fact, 90 percent of these companies have 100 or fewer employees. *Technology, Innovation, and the Costs of Health Care: Hearing Before the Joint Econ. Comm.*, 108th Cong. (2003) (Testimony of Advanced Medical Technology Association).

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[2] AdvaMed was formerly the Health Industry Manufacturers Association ("HIMA").

One of the inevitable consequences of innovation in health care technology is that a small percentage of patients suffer injuries that they allege were caused by defective products. Thus, medical technology companies, like most other businesses, purchase liability insurance to cover the risks of these injuries. Like most purchasers of insurance, including both corporations and individuals, AdvaMed's members pay premiums to insurance companies for policies that require a certain deductible amount to be met before the insurance company begins paying on claims.

AdvaMed and its members have a significant interest in the outcome of this litigation. Nearly all of AdvaMed's members do now or will in the future face tort litigation concerning the medical devices they manufacture. The Eleventh Circuit's decision in this case would transform all of AdvaMed's members into "self-insured plans" with respect to that litigation with resulting liability under the Medicare Secondary Payer statute. This creates significant uncertainty for AdvaMed members who have chosen to settle such litigation in the past.

ARGUMENT

I. THE DECISION BELOW CONFLICTS WITH OTHER CIRCUITS' HOLDINGS AND WITH THE STATUTE'S LANGUAGE, HISTORY AND IMPLEMENTING REGULATIONS.

As its name suggests, the Medicare Secondary Payer statute ("MSP"), 42 U.S.C. § 1395y(b)(2), ensures that the Medicare program is not the primary insurer of a Medicare beneficiary's medical costs if there is a "primary plan" that also has responsibility to pay for those costs. During the period relevant to this case, the statute provided that, where the government paid Medicare funds to a beneficiary, it could seek reimbursement from an entity "which is required or responsible" to pay the beneficiary under a "primary plan" *or*

which has "received payment" from a "primary plan." *Id.* § 1395y(b)(2)(B)(ii).[3] "[P]rimary plan" is defined to include health plans, automobile or liability insurance plans and "self-insured plan[s]." *Id.* § 1395y(b)(2)(A). The statute does not define a "self-insured plan," but regulations promulgated by the Centers for Medicare and Medicaid Services ("CMS") define the term as "a plan under which an individual, or a private or governmental entity, carries its own risk *instead of taking out insurance with a carrier.*" 42 C.F.R. § 411.50(b)(2) (emphasis added). The government may recover double damages from a liable "primary plan." 42 U.S.C. § 1395y(b)(2)(B)(ii).

The Eleventh Circuit acknowledged that petitioners "had at least some liability [insurance] coverage," Pet. App. 5a—a fact that placed them outside the scope of the CMS definition of "self-insured plans." The lower court nevertheless concluded that the term "self-insured plan" should be interpreted to include petitioners because they had "plan[ned] ahead of time to assume responsibility and liability for certain risks up to a designated amount" by paying a deductible. *Id.* at 46a. The court rejected the view, adopted by the district court as well as the Fifth Circuit, that "self-insurance" requires a formal set-aside of funds to cover future liabilities. *Id.* at 46a-47a. Thus, under the Eleventh Circuit's holding, only those entities that carry liability insurance that is unlimited in coverage and scope would not be considered a "self-insured plan."

The court also held that because petitioners may have received reimbursement from their liability insurance carriers for a portion of the settlement amount, they had "received payment" from a "primary plan." Pet. App. 66a-67a. Accordingly, the government was entitled to seek both the funds that the petitioners paid into the settlement as part of

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[3] All references are to the MSP as it existed during the relevant time period.

the deductible portion of their liability insurance, as well as monies from petitioners' liability insurance companies that passed through petitioners and into the settlement fund.

The Eleventh Circuit's decision has created a sharp split of authority among the courts of appeals. The decision conflicts with the Second and Fifth Circuits' interpretation of a "self-insured plan," and with the District of Columbia Circuit's construction of the "received payment" prong of the MSP.

A. In *Thompson* v. *Goetzmann*, 337 F.3d 489 (5th Cir. 2003) (per curiam), the Fifth Circuit noted that six federal district courts and one bankruptcy court had already rejected the government's interpretation of the MSP to cover alleged tortfeasors who settle with injured plaintiffs—the same overly broad approach found in this case—as a "uniformly feckless" effort to expand the interpretation of the MSP. *Id.* at 503, 494. The *Goetzmann* court determined that a company's negotiation of a settlement with a litigant does not represent a "self-insurance" plan. See *id.* at 498. Instead, a corporation that acts as a "self-insured plan" would maintain a fund and establish disbursement rules like any other insurance carrier. See *id.* at 498-99.

Similarly, in *Mason* v. *American Tobacco Co.*, 346 F.3d 36, 40 (2d Cir. 2003), *cert. denied*, 72 U.S.L.W. 3580 (May 17, 2004) (No. 03-1270), the Second Circuit rejected the argument that a company that has not established a separate fund for its legal liabilities under a formal plan can nevertheless qualify as a "self-insured plan" if it "'retain[s] any portion of that risk, no matter how small.'" *Id.* at 40-41. Like the district court below, the Second Circuit concluded that the MSP was not the appropriate procedural vehicle to sue insured tortfeasors and dismissed the government's misguided attempt to categorize the defendant companies as self-insured plans. *Id.*

In the decision below, the Eleventh Circuit acknowledged its disagreement with the Fifth Circuit's conclusion in

Goetzmann that a self-insured plan involves a set-aside of funds to pay future liabilities and defines disbursement rules. See Pet. App. 49a. It attempted to dismiss that conclusion, however, as "dicta." *Id.* But, as petitioners have demonstrated, Pet. 18, the Fifth Circuit's construction of the term "self-insured plan" was essential to its judgment. The Third Circuit has recognized, moreover, that the Eleventh Circuit's definition of a "self-insured plan" creates a circuit split with the Fifth Circuit on this issue. See *Fanning* v. *United States*, 346 F.3d 386, 400 n.13 (3d Cir. 2003) ("[W]e note that the government's argument that a 'self-insured plan' includes a fund created by a tortfeasor to settle litigation has engendered a circuit split."), *petition for cert. filed*, 72 U.S.L.W. 3616 (Mar. 15, 2004) (No. 03-1327).

B. The Eleventh Circuit's decision also departs from the D.C. Circuit's conclusion in *Health Insurance Ass'n of America, Inc.* v. *Shalala*, 23 F.3d 412 (D.C. Cir. 1994), that the MSP does not impose liability on an entity that acts as a conduit for transferring insurance payments. The D.C. Circuit disagreed with the government's argument that the MSP permitted recovery actions against third-party administrators that issued payments on behalf of an insurer. See *id.* at 416-17. Instead, the D.C. Circuit held that the government should pursue not the administrators but, rather, the insurer. *Id.* Squarely contradicting the D.C. Circuit's well-reasoned analysis, the Eleventh Circuit found that the government could sue the insured tortfeasors who pass through insurance payments to the final recipients of the payment. See Pet. App. 66a-67a.

C. As the analysis of the Second, Fifth and D.C. Circuits confirms, the decision below is plainly wrong. By its terms, the MSP allows recovery from a "'primary plan' [which] means a group health plan or large group health plan . . . and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance." 42 U.S.C. § 1395y(b)(2)(A). It

is well recognized that, "when a general word or phrase follows a list of specific persons or things, the general word or phrase will be interpreted to include only persons or things of the same type as those listed." *United States* v. *Ryan-Webster*, 353 F.3d 353, 365 (4th Cir. 2003). The district court in the *Mason* case followed that principle and recognized what the Eleventh Circuit did not.

> The list of responsible entities . . . primarily includes various types of insurance companies . . . . The logical inference is that a "self-insured plan" as included in that list means an entity that has assumed a posture similar to that of an insurance company. Defendants are not insurance companies and they have no apparent agreement or policy to be self-insured plans covering general tort claims.

Mason v. *American Tobacco Co.*, 212 F. Supp. 2d 88, 91 (E.D.N.Y. 2002) (citations omitted), *aff'd*, 346 F.3d 36 (2d Cir. 2003).

In addition, because the MSP provides for double damages, it is a penalty statute. It is of course well settled that "the law favors the narrow construction of penalty statutes." *In re Tax Refund Litig.*, 766 F. Supp. 1248, 1257 (E.D.N.Y. 1991), *aff'd in part, rev'd in part on other grounds*, *In re MDL-731 Tax Refund Litig.*, 989 F.2d 1290 (2d Cir. 1993); see also *Commissioner* v. *Acker*, 361 U.S. 87, 91 (1959). Yet the Eleventh Circuit adopted a breathtakingly expansive interpretation that treats as "self-insured" every tortfeasor whose insurance policy includes a deductible. See *infra* at 9-12.

Nothing in the MSP's legislative history supports this sweeping construction; to the contrary, it is clear that Congress did not intend the term "self-insured plan" to subject all insured tortfeasors whose policies include deductibles to double damages. Congress added the provision now in dispute to the Medicare statute in 1980. See Pub. L.

No. 96-499, tit. IX, § 953, 94 Stat. 2609, 2647 (1980). The language originated in the House and was designed to conserve Medicare funds in cases of automobile accidents where medical "services could have been paid for by a *private insurance carrier*." H.R. Rep. No. 96-1167, at 389 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5752 (emphasis added). The Senate amendment reflected a similar concern and referred to situations in which "[M]edicare would be the secondary payer in any case where care can be paid for under any liability insurance policy (including an automobile insurance policy)." H.R. Conf. Rep. No. 96-1479, at 133 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5903, 5924. In conference, the House and Senate agreed to include, as a subset of liability insurance, those arrangements defined as "self-insured" plans. *Id.*

In amendments to the MSP in 1989, neither House nor Senate indicated any intent to reach all tortfeasors. Congress confirmed that Medicare could recover costs "from *the liability insurer* of the person who caused the injury" under the MSP in cases involving liability insurance. H.R. Conf. Rep. No. 101-386, at 818-19 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3421-22 (emphasis added). In 1995, Congress again noted in conference that the MSP program "identif[ies] situations where another *health care plan* should be . . . the primary payer." H.R. Rep. No. 104-87(I), at 4 (1995) (emphasis added). Thus, "the statute's clear purpose was to grant the Government a right to recover Medicare costs from insurance entities," *United States* v. *Philip Morris Inc.*, 116 F. Supp. 2d 131, 146 n.22 (D.D.C. 2000), and its "legislative history . . . provides no indication of a Congressional design to include an enormous group of potential tortfeasors as primary payors subject to double recovery under the statute." *Mason*, 212 F. Supp. 2d at 93.

Finally, Congress clearly knows how to impose reimbursement liability on tortfeasors. The Medical Care Recovery Act permits the government to collect from

tortfeasors—whether insured, uninsured or self-insured—the reasonable value of certain medical care provided to or paid for by the United States. See 42 U.S.C. § 2651(a). Congress, however, failed to include tortfeasors in the MSP, so it is utterly implausible to assume that Congress intended the term "self-insured plan" to confer a right to recover reimbursement of Medicare payments from all tortfeasors whose insurance policies include deductibles.

II. ALL TORTFEASORS, WHETHER INSURED OR UNINSURED, ARE SUBJECT TO MSP LIABILITY UNDER THE ELEVENTH CIRCUIT'S HOLDING.

The lower court's holding brings most, if not all, of AdvaMed's members—and virtually every business and individual in the nation—within the scope of the definition of a "self-insured plan" and renders them responsible for Medicare costs as a "primary plan." AdvaMed's members, like most businesses and individuals, protect against future losses by purchasing insurance. The insurance coverage purchased protects the insured from a specified amount or percentage of those losses, but insurance rarely covers the entire amount of potential damages. Insurers issue policies that employ deductibles, co-payments or their functional equivalents that require the insured to pay for some portion of the insured loss. Insurers do this to protect against the problem of "moral hazard," which arises when the behavior of the insured changes after insurance is obtained. In other words, to prevent the insured from assuming excessive risks, insurance policies require that the insured pay some portion of the loss.

Deductibles and their functional equivalents vary in amount, with deductibles for companies generally being larger than those for individuals. It is also common for larger companies to have larger deductibles than smaller companies. In addition, the *timing* of the deductible payment by the

insured varies. Some policies require the insured to pay for the loss up to the amount of the deductible *before* the insurer pays and some require the insured to reimburse the insurer *after* the insured makes the payment. Thus, the policy may allow or require the insured to pay for the entire damage amount and then the insurance company will reimburse the insured up to the policy limits minus the deductible.

A very small percentage of policies do not require the insured to pay any deductible or its equivalent and will cover losses without any contribution by the insured. Such "first-dollar" policies are often prohibitively expensive for companies, especially small technology companies like many in the medical device industry, because the insurer must be compensated for agreeing to ignore the moral hazard problem. Even in these first-dollar policies, however, the insurer rarely covers an infinite amount of potential losses. All policies of which we are aware in the medical device industry have a specified upper limit or cap on the amount that the insurer will pay for any given occurrence.

Automobile liability insurance is a good example of the way liability insurance works in practice—and it is also the quintessential type of insurance that the MSP was meant to reach. When an individual or a company's employee covered by an automobile policy gets into an accident, the insurance company will cover damages up to a certain pre-determined amount and the insured must pay a deductible portion of those damages, typically in the range of $100 to $500 per accident. The policy may require the insured to pay that amount upfront or it may collect the deductible amount after the insurance company has paid. Some large companies with large fleets of vehicles choose to self-insure rather than to pay some other entity to insure them. To do so, state laws require them to have administrative procedures in place for processing claims and to keep deposits or have other financial arrangements that will cover potential losses. See, *e.g.*, Del. Code Ann. tit. 21, § 2904.

Sensibly understood, therefore, the term "self-insured plan" reaches only large entities that seek to save on insurance costs by performing themselves the same risk-spreading and risk-management functions that private insurers perform. Rather than accept this commonsense meaning, the court below engaged in intellectual gymnastics to hold that the payment of a deductible, even in the absence of a plan to set aside monies for eventual liabilities, transformed petitioners from insureds to operators of "self-insured plans" because the deductibles required petitioners to cover some of the risk of loss. The Second Circuit rejected a similar argument precisely because of its sweeping and implausible implications. Such an interpretation "turns *every* corporation into an insurance company subject to suit under the MSP statute." *Mason*, 346 F.3d at 40.

> "Its logical implication is that any [corporate] entity with a risk of legal liability which chooses to retain any portion of that risk, no matter how small, may be pursued under MSP on the ground that it is a 'self-insured plan.' . . . The practical effects of [this] conception of MSP liability would transform the statute, meant primarily for use against insurers, *see Philip Morris [I]*, 116 F. Supp. 2d at 146 n. 22, into the very 'across-the-board procedural vehicle for suing tortfeasors,' which this Court has already declared impermissible. *Id.* at 135."

Id. (alterations and omission in original) (quoting *United States* v. *Philip Morris, Inc.*, 156 F. Supp. 2d 1, 7-8 (D.D.C. 2001)).

The Eleventh Circuit's holding admits of no rational limiting principles. *All* tortfeasors who have purchased insurance will be considered "self-insured plans" because they, like petitioners here, cover some of their risk of liability through either deductibles or caps on insurance coverage or both. Perhaps more disturbing is the fact that an insured with *any* deductible, no matter how small, would be subjected to

the government's collection practices for the entire amount of the Medicare expenditure, not just up to the amount of the deductible.

The second half of the Eleventh Circuit's holding—that petitioners "received payment" from a "primary plan" because their liability policies may have *reimbursed* petitioners rather than paying into the settlement fund directly—elevates form over substance and produces a nonsensical result that is inconsistent with the MSP and reality. As discussed above, liability insurers may pay for a loss either by paying the injured party directly or by reimbursing the insured after the insured has paid the injured party. In either case, it is the insurer, not the insured, that effectively pays the injured party. The payments may pass through the insured to the injured party and the fact that the insured "retains" the payment is an issue only of the timing of that payment. To leave the Eleventh Circuit's holding intact would, for no apparent reason in the statute, capture those entities whose insurers pay after settlement rather than before.

III. THE DECISION BELOW WILL UPSET PREVIOUS SETTLEMENTS, DISCOURAGE FUTURE SETTLEMENTS AND IMPOSE SIGNIFICANT COSTS ON SOCIETY.

The Eleventh Circuit has permitted the government to evade its statutory obligation to seek reimbursement of payments made to class plaintiffs who are also Medicare beneficiaries. Rather than intercept payments made from the settlement fund, the government waited over four years after settlement to seek reimbursement from petitioners outside of, and in addition to, the settlement funds already paid.

By reading the statute to allow the government to seek reimbursement from tortfeasors long after settlement has been entered, the Eleventh Circuit has injected uncertainty into the settlement process that will upset expectations based on settlements that have already occurred and will complicate

future settlements in a manner that Congress could not have intended. Innovators in general, and AdvaMed's members in particular, face the possibility of litigation over the use of their products as a regular part of their business. Settling such litigation is an efficient way to bring certainty and finality to the injured plaintiffs and to the defendants. The Eleventh Circuit's holding drastically reduces this certainty and eliminates closure associated with settlement because the government may or may not later seek additional damages directly from the tortfeasor above and beyond the amount paid in the settlement.

These concerns are particularly acute in many class action lawsuits where the exposure is large and settlements are sometimes structured mainly to compensate plaintiffs for their economic damages. For medical injuries, healthcare costs represent about one-half of total economic losses. E.J. Thomas et al., *Costs of Medical Injuries in Utah and Colorado*, 36 Inquiry 255 (1999). Accordingly, reimbursement sought by the government against alleged tortfeasors after doubling under the MSP can constitute a significant percentage of the total amount of a settlement fund created for the plaintiffs. To subject past settlements to such unexpected additional liability is profoundly unfair. Under the Eleventh Circuit's ruling, the government will be free to reopen numerous medical device liability cases AdvaMed's members had settled in good faith believing that the litigation and liability would come to an end.

On a prospective basis, the risks of such increased liability can only complicate and hinder the already difficult process of resolving mass tort claims. There are, for example, a number of pending medical device liability cases that have been consolidated by the Judicial Panel on Multidistrict Litigation and each involves a multitude of claims that might subject the parties to the uncertainty created by the Eleventh Circuit's novel holding. See, *e.g.*, *In re St. Jude Med., Inc., Silzone Heart Valves Prods. Liability Litig.*, No. MDL-1396,

No. 01-md-1396(JRT) (D. Minn. transferred Apr. 18, 2001); *In re Sulzer Orthopedics, Inc., Hip Prosthesis & Knee Prosthesis Prods. Liability Litig.*, No. MDL-1401, No. 01-cv-9000 (N.D. Ohio transferred June 19, 2001). Because mass tort litigation "clogs dockets for decades, creating burdens on the judicial system and delaying relief for injured parties[,] . . . . the general policy of federal courts to promote settlement before trial is even stronger in the context of large-scale class actions." *Icicle Seafoods, Inc.* v. *Baker (In re Exxon Valdez)*, 229 F.3d 790, 795 (9th Cir. 2000); see also *Isby* v. *Bayh*, 75 F.3d 1191, 1196 (7th Cir. 1996) ("Federal courts naturally favor the settlement of class action litigation."); *Franklin* v. *Kaypro Corp.*, 884 F.2d 1222, 1229 (9th Cir. 1989) ("'[I]t hardly seems necessary to point out that there is an overriding public interest in settling and quieting litigation. This is particularly true in class action suits. . . .'"). By creating such a strong disincentive to settle, the Eleventh Circuit, in the absence of any Congressional direction to do so and in contravention of judicial policy, read too much into the MSP.

Perhaps more importantly from a societal standpoint, the decision will have a detrimental impact on the number of new medical devices that reach patients who need them. Because the government's recoveries under the court's decision increase the amount of expected loss from injuries beyond the cost of actual injuries, innovators will be less inclined to place products on the market. As the marginal cost of placing the technology on the market exceeds the marginal benefit the innovator expects to recoup from its investment, the innovator will expect a net loss on the sale of the product. Technologies that are beneficial but only marginally profitable will be especially affected by the lower court's mistaken ruling.

IV. THE SUBSEQUENT AMENDMENT OF THE MSP DOES NOT UNDERMINE THE IMPORTANCE OF THE ELEVENTH CIRCUIT'S RULING.

Petitioners have explained that, even if the MSP's recently amended definition of "primary plan" is understood as a retroactive codification of the lower court's interpretation of "self-insured plan," the circuit split that the decision below creates will continue to affect thousands of entities and individuals who have allegedly violated their payment obligations to the government. Pet. 26-30. We note that there is an alternative, and more limited, interpretation of the amended definition that likewise would not eliminate the far-reaching impact of the Eleventh Circuit's holding that insured tortfeasors whose policies include deductibles are not "self-insured plans."

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066, amended the definition of "primary plan" by adding the following clause:

> "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise) in whole or in part."

Id. § 301(b)(1), sec. 1862(b)(2), 117 Stat. at 2222. Notably, this language does *not* refer to entities that purchase insurance policies *with deductibles*. To the contrary, it focuses on those who *fail* to purchase insurance.

As AdvaMed has explained, permitting the government to seek Medicare reimbursement from insured tortfeasors whose policies include deductibles is an extraordinary—indeed, startling—legal weapon. Because Congress is not expected to "hide elephants in mouseholes," *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001), it must express its intent to adopt extraordinary measures in clear and unambiguous terms. *MCI Telecomms. Corp.* v. *AT&T Co.*,

512 U.S. 218, 231 (1994). Congress could have easily expressed an intent to ratify the decision below, simply by referring to entities that carry risk "by failing to purchase insurance or by purchasing insurance policies with deductibles or their functional equivalents," yet it failed to do so. Accordingly, the amended definition of "primary plan" should not be understood to embrace insured tortfeasors whose policies include deductibles unless that is the only meaning the language can bear.

In fact, the amended language is susceptible of another, entirely plausible meaning. As noted, the statutory language itself focuses on an entity that carries its own risk by virtue of "a *failure* to obtain insurance." The language thus appears to be directed at situations where the government seeks reimbursement from someone who has no insurance. Although the statute refers to entities that carry their own risk "whether by a failure to obtain insurance *or otherwise*," the "or otherwise" clause is most plausibly understood to refer to actions (or inactions) that are comparable to a failure to purchase insurance, such as the failure to pay premiums that results in a lapse of coverage. See, *e.g.*, *Jarecki* v. *G.D. Searle & Co.*, 367 U.S. 303, 307 (1961) (the maxim that "a word is known by the company it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress"). Similarly, the reference to carrying risk "in whole *or in part*" does not inescapably refer to carrying risk through deductibles; it can also refer to coverage that is partial in a temporal sense, because, for example, an insured allowed coverage to lapse and thus was covered only for part of a relevant time period. This alternative interpretation is plainly to be preferred over one in which the opaque phrases "or otherwise" and "in part" work a sea-change in the commonsense and widespread understanding that entities that purchase liability coverage from insurance companies are not self-insurers simply

because their policies have deductibles. See *MCI Telecomms. Corp.*, 512 U.S. at 231 (Congress does not effectuate sweeping, industry-wide changes through "such a subtle device").

Under this alternative interpretation, Congress has not repudiated or otherwise undermined the Second Circuit's conclusion in *Mason* that the mere retention of some portion of liability risk does not constitute a form of "self-insurance." Similarly, this alternative interpretation does not create the impediments to settlement and the disincentives to innovation that the Eleventh Circuit's breathtaking interpretation of the MSP creates. Accordingly, the amended definition of "primary plan" does not undermine the continued importance of the lower court's erroneous ruling, or the need for this Court's review. To the contrary, under this alternative interpretation of the amended definition, the decision below continues to present an issue of great importance not only for insured manufacturers of medical devices, but literally for every business or individual that purchases insurance policies with deductibles.

CONCLUSION

For the foregoing reasons, *amicus curiae* respectfully ask this Court to grant the petition for a writ of certiorari to the United States Court of Appeals for the Eleventh Circuit.

Respectfully submitted,

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